

## REMARKS

### 1. Formal Matters

#### a. Status of the Claims

Claims 1-16 are pending in this application. Claims 1-16 are hereby cancelled without prejudice to pursuing these claims in a continuing application. Claims 17-36 are new. Upon entry of these amendments, claims 17-36 are pending and under active consideration. Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present application.

#### b. Amendments to the Claims

New claim 17 recites a nucleic acid consisting of 18 to 120 nucleotides, support for which may be found throughout the application including claims 1-3 as originally filed. New claim 17 also recites that the sequence of the nucleic acid may comprise at least 18 consecutive nucleotides of SEQ ID NO: 8797, support for which may be found at paragraph [9179] as originally filed. Paragraph [9179] recites:

GR672 FOLDED PRECURSOR RNA is naturally processed by cellular enzymatic activity into at least 2 separate GAM precursor RNAs, GAM334 PRECURSOR and GAM390 PRECURSOR, each of which GAM precursor RNAs being a hairpin shaped RNA segment, corresponding to GAM PRECURSOR RNA of Fig. 8.

SEQ ID NOS: 5135 and 6033 represent the sequences of GAM334 and GAM390, respectively, each of which sequence is contained in the application as originally filed. GAM334 (SEQ ID NO: 5135) is located on the plus strand of human chromosome 12 at positions 52,675,453 to 52,675,531. GAM390 (SEQ ID NO: 6033) is located on the plus strand of human chromosome 12 at positions 52,675,280 to 52,675,364. SEQ ID NO: 8797 (GR672) represents the sequence of the plus strand of human chromosome 12 at positions 52,675,280 to 52,675,531. Therefore, SEQ ID NO: 8797 (GR672) represents the sequence of GAM390 (SEQ ID NO: 6033), GAM334 (SEQ ID NO: 5135), and the intervening 88 base pairs in the genomic sequence (positions 52,675,365 to 52,675,452).

Claim 17 is also amended to recite that the nucleic acid may be: an RNA equivalent of (a), support for which may be found in the application as originally filed including at claim 1.

Claim 17 is also amended to recite that the nucleic acid may be: a sequence at least 60/85 identical to (a) or (b), support for which may be found at claim 1 and the application as originally

filed. As described hereinabove, GR672 (represented by SEQ ID NO: 3760) encodes GAM390 (represented by SEQ ID NO: 6033). GAM390 forms a hairpin, as shown at Table 1, lines 2527-2532 and paragraph 5636 of the application as originally filed. The sequence of GAM390 (SEQ ID NO: 6033) is 85 nucleotides in length. Within the predicted hairpin formed by the nucleic acid of SEQ ID NO: 6033, 60 complementary nucleotides are paired.

Claim 17 is also amended to recite that the nucleic acid may be: the complement of any one of (a)-(c), support for which may be found at claim 1 and paragraphs 4796 and 5636 of the application as originally filed.

New claim 18 recites the nucleic acid of claim 17, wherein the at least 18 nucleotides is of a sequence selected from the group consisting of SEQ ID NOS: 5135 and 6033, support for which can be found at Table 1, lines 2167-2172 and 2527-2532, and paragraphs 4795 and 5635 of the application as originally filed.

New claim 19 recites a nucleic acid of claim 17, wherein the at least 18 nucleotides is of a sequence selected from the group consisting of SEQ ID NOS: 5136 and 6034, support for which can be found at Table 1, lines 2167-2172 and 2527-2532, and paragraphs 4797 and 5637 of the application as originally filed.

New claim 20 recites a nucleic acid of claim 17, wherein the nucleic acid consists of 18 to 24 nucleotides, support for which can be found at claims 1-3 as originally filed.

New claim 21 recites a nucleic acid with a sequence consisting of (a) SEQ ID NO: 8797 (b) an RNA equivalent of (a); (c) a sequence at least 60/85 identical to (a) or (b); or (d) the complement of any one of (a)-(c), support for which may be found as described above for new claim 17.

New claim 22 recites a nucleic acid of claim 17, wherein the at least 18 nucleotides is of a sequence selected from the group consisting of SEQ ID NOS: 5135 and 6033, support for which can be found as described for new claim 18.

New claim 23 recites a nucleic acid of claim 21, wherein the at least 18 nucleotides is of a sequence selected from the group consisting of SEQ ID NOS: 5136 and 6034, support for which can be found as described for new claim 19.

New claim 24 recites a nucleic acid of claim 21, wherein the nucleic acid consists of 18 to 24 nucleotides, support for which can be found as described for new claim 20.

New claim 25 recites a nucleic acid of claim 18, wherein the nucleic acid is an RNA, support for which can be found at claim 1 as originally filed and at paragraphs 4796 and 5636 of the application as originally filed.

New claim 26 recites a nucleic acid of claim 22 wherein the nucleic acid is an RNA, support for which can be found at claim 1 as originally filed and at paragraphs 4796 and 5636 of the application as originally filed.

New claim 27 recites a nucleic acid of claim 25, wherein the nucleic acid is capable of modulating expression of a target gene, support for which can be found at claim 3 as originally filed.

New claim 28 recites a nucleic acid of claim 26, wherein the nucleic acid is capable of modulating expression of a target gene, support for which can be found at claim 3 as originally filed.

New claim 29 recites a nucleic acid of claim 27, wherein the nucleic acid is at least 12/22 complementary to a binding site sequence of 18 to 24 nucleotides of a target gene, support for which may be found at Table 2, lines 33507-33546, which show that among all listed target binding sites of the nucleotide represented by SEQ ID NO: 5135, the sequence of which is included in the sequence of SEQ ID NO: 8797, at the lowest level of complementarity a target binding site of 22 nucleotides has 12 nucleotides complementary to the sequence of SEQ ID NO: 5136. New claim 29 also recites that the binding site sequence is located in an untranslated region of RNA encoded by the target gene, support for which can be found at paragraphs 20, 4799, and 5639 of the application as originally filed.

New claim 30 recites a nucleic acid of claim 28, wherein the nucleic acid is at least 12/22 complementary to a binding site sequence of 18 to 24 nucleotides of a target gene and wherein the binding site sequence is located in an untranslated region of RNA encoded by the target gene, support for which can be found as described for new claim 29.

New claim 31 recites a vector comprising an insert, wherein an insert consists of the nucleic acid of claim 17, support for which can be found at paragraph 22 of the application as filed.

New claim 32 recites a vector comprising an insert, wherein an insert consists of the nucleic acid of claim 21, support for which can be found at paragraph 22 of the application as filed.

New claim 33 recites a probe comprising an insert, wherein an insert consists of the nucleic acid of claim 17, support for which can be found at paragraph 26 of the application as filed.

New claim 34 recites a probe comprising an insert, wherein an insert consists of the nucleic acid of claim 21, support for which can be found at paragraph 26 of the application as filed.

New claim 35 recites a gene expression inhibition system comprising the vector of claim 31 and a means for inserting said vector into a cell, support for which can be found at paragraphs 24-25 as originally filed.

New claim 36 recites a gene expression inhibition system comprising the vector of claim 32 and a means for inserting said vector into a cell, support for which can be found at paragraphs 24-25 as originally filed.

**c. Amendments to the Specification**

Paragraph [0051] is amended to assign SEQ ID NO: 8788 to the sequence shown in Fig. 21A in compliance with 37 C.F.R. §§ 1.821 - 1.825.

The second replacement paragraph for paragraph [0052] filed in the Preliminary Amendment filed on January 10, 2005 has been amended to assign SEQ ID NO: 8789 to the sequence shown in Fig. 22A in compliance with 37 C.F.R. §§ 1.821 - 1.825.

The fifth replacement paragraph for paragraph [0052] filed in the Preliminary Amendment filed on January 10, 2005 has been amended to assign SEQ ID NO: 8790 to the sequence shown in Fig. 23A in compliance with 37 C.F.R. §§ 1.821 - 1.825.

Paragraph [0123] has been amended to assign SEQ ID NOS: 8791-8796 to the listed sequences in compliance with 37 C.F.R. §§ 1.821 - 1.825. Paragraph [0123] has also been amended to correct typographical errors.

**d. Elections/Restrictions**

Groups I-III

At pages 3-6 of the Office Action, the Examiner requires restriction to one of the following inventions under 35 U.S.C. 121:

- I. Claims 1-10, 13, 14, and 16, drawn to a bioinformatically detectable novel gene, a vector comprising said novel gene, a probe comprising

said novel gene, and a vector inserter comprising said probe and a gene expression detector.

- II. Claims 11 and 12, drawn to a method of selectively inhibiting translation of at least one gene.
- III. Claim 15, drawn to a method of selectively detecting gene expression of at least one gene.

Applicant elects without traverse Group I, which now is considered claims 17-36, drawn to an isolated nucleic acid, a vector comprising said nucleic acid, a probe comprising said nucleic acid, and a gene expression inhibition system comprising said vector and a means for inserting said vector into a cell.

**e. Sequence Election Requirement for All Groups**

At page 6 of the Office Action, the Examiner requires restriction to a single sequence. Applicant elects with traverse nucleic acids related to SEQ ID NO: 8797 for further prosecution.

The Examiner is permitted under 35 U.S.C. 121 to issue a restriction requirement between independent and distinct inventions. However, the Director has partially waived the requirements of 37 C.F.R. § 1.141 *et seq.* to permit a reasonable number of nucleotide sequences to be claimed in a single application. *See Examination of Patent Applications Containing Nucleotide Sequence*, 1192 O.G. 68 (November 19, 1996). It has been determined that normally ten sequences constitute a reasonable number for examination purposes absent an exceptional case. *See* MPEP 803.04.

The Examiner has failed to demonstrate that the claimed sequences are an exceptional case necessitating that the number of sequences to be selected be less than ten. Applicant respectfully submits that the Examiner is impermissibly disregarding the waiver of 37 C.F.R. § 1.141 *et seq.* Accordingly, Applicant respectfully requests reconsideration of the restriction requirement and the opportunity to elect ten sequences for further prosecution.

**f. Species Election Regarding Target Genes in Group I**

At page 7 of the Office Action, the Examiner requires election of a single disclosed species for Group I under 35 U.S.C. § 121. Applicant without traverse elects B3GALT2 which has the sequence of SEQ ID NO: 5137.

**2. Conclusion**

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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